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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/258,682	02/26/99	FAUSTMAN	D 11275/79290

EXAMINER	
NOLAN, P	
ART UNIT	**PAPER NUMBER**
1644	11

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DATE MAILED: 03/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/258,682	Faustman et al.
Examiner	**Group Art Unit**
Patrick Nolan	1644

☒ Responsive to communication(s) filed on *Jan 8, 2001*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-65* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-65* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Part III DETAILED ACTION

1. Upon further consideration the Restriction set forth in Paper No. 8 is vacated and the following restriction is set forth.

2. Claims 1-65 are pending.

Restriction/Election

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-7, drawn to a method of detecting an autoimmune disease by detecting proteosome activity, classified in class 435, subclass 7.4.

Group II. Claims 8-13, drawn to a method of detecting an autoimmune disease by detecting protein ubiquination, classified in class 435 subclass 7.8.

Group III. Claims 14-19, drawn to a method of detecting an autoimmune disease by detecting protein phosphorylation, classified in class 435 subclass 7.1.

Group IV. Claims 20-26, drawn to a method of detecting an autoimmune disease by detecting NFKB activity, classified in class 435 subclass 7.8.

Group V. Claims 27-33, drawn to a method of detecting autoimmune diseases by detecting cell survival or growth, classified in class 435 subclass 29.

Group VI. Claims 34-36, 38-43, 46-51, 54-59 and 62-64, drawn to a method of treating an autoimmune disease by administering ubiquitin-activating enzyme (E1), classified in class 424, subclass 94.1.

Group VII. Claims 34-36, 38-43, 46-51, 54-59 and 62-64, drawn to a method of treating an autoimmune disease by administering ubiquitin-conjugating enzyme (E2), classified in class 424, subclass 94.1.

Group VIII. Claims 34-36, 38-43, 46-51, 54-59 and 62-64, drawn to a method of treating an autoimmune disease by administering ubiquitin-ligases (E3), classified in class 424, subclass 94.1.

Group IX. Claims 34-35, 38-39, 40-42, 46-50, 54-58 and 62-64, drawn to a method of treating autoimmunity by administering a nucleic acid, classified in class 514 subclass 44.

Group X. Claims 34, 37-40 drawn to a method of treating

autoimmunity by administering a ribozyme which restores protein ubiquitinating enzyme function, classified in class 514, subclass 44.

Group XI. Claims 34, 37-40 drawn to a method of treating autoimmunity by administering an antisense molecule which restores protein ubiquitinating enzyme function, classified in class 514, subclass 44.

Group XII. Claims 41-43, 46-51, 54-59 and 62-64, drawn to a method of treating autoimmunity by administering a mutant or wild type NFkBp50 molecule, classified in class 424 subclass 184.1.

Group XIII. Claims 41-43, 46-50, drawn to a method of treating autoimmunity by administering a NFkBp52 molecule, classified in class 424 subclass 184.1.

Group XIV. Claims 41-43, 46-50, drawn to a method of treating autoimmunity by administering a competitor of IkB that does not bind NfkBp50 or NFkB65, classified in class 424 subclass 184.1.

Group XV. Claims 41-43, 46-51, 54-59 and 62-64, drawn to a method of treating autoimmunity by administering a mutant or wild type NFkBp65 molecule, classified in class 424 subclass 184.1.

Group XVI. Claims 41-43, 46-51, 54-59 and 62-64, drawn to a method of treating autoimmunity by administering TNF-alpha, classified in class 424 subclass 85.1.

Group XVII. Claims 41-43, 46-51, 54-59 and 62-64, drawn to a method of treating autoimmunity by administering E-selectin, classified in class 424 subclass 184.1.

Group XVIII. Claims 41-43, 46-51, 54-59 and 62-64, drawn to a method of treating autoimmunity by administering I-cam, classified in class 424 subclass 184.1.

Group XIX. Claims 41-43, 46-51, 54-59 and 62-64, drawn to a method of treating autoimmunity by administering V-cam, classified in class 424 subclass 184.1.

Group XX. Claims 41-43, 46-51, 54-59 and 62-64, drawn to a method of treating autoimmunity by administering IL-2, classified in class 424 subclass 85.2.

Group XXI. Claims 41-43, 46-51, 54-59 and 62-64, drawn to a method of treating autoimmunity by administering IL-6, classified in class 424 subclass 85.2.

Group XXII. Claims 41-43, 46-51, 54-59 and 62-64, drawn to a method of treating autoimmunity by administering GCSF, classified

in class 424 subclass 85.1.

Group XXIII. Claims 41-43, 46-51, 54-59 and 62-64, drawn to a method of treating autoimmunity by administering Interferon-beta, classified in class 424 subclass 85.6.

Group XXIV. Claims 41-43, 46-51, 54-59 and 62-64, drawn to a method of treating autoimmunity by administering LMP2, classified in class 424 subclass 184.1.

Group XXV. Claims 41-43, 46-51, 54-59 and 62-64, drawn to a method of treating autoimmunity by administering LMP7, classified in class 424 subclass 184.1.

Group XXVI. Claims 41-43, 46-51, 54-59 and 62-64, drawn to a method of treating autoimmunity by administering protein kinase, classified in class 424 subclass 94.1.

Group XXVII. Claims 41-43, 46-51, 54-59 and 62-64, drawn to a method of treating autoimmunity by administering proteosome subunit, classified in class 424 subclass 94.1.

Group XXVIII. Claims 41-43, 46-51, 54-59 and 62-64, drawn to a method of treating autoimmunity by administering antibody to CF-2, classified in class 424 subclass 130.1.

Group XXIX. Claims 41-43, 46-51, 54-59 and 62-64, drawn to a method of treating autoimmunity by administering antibody to IkB, classified in class 424 subclass 130.1.

Group XXX. Claims 41, 44-49, 52-57 and 60-64, drawn to a method of treating an autoimmune disease by administering a ribozyme or a DNA molecule which encodes it, wherein said nucleic acid is directed against CF-2, classified in 514, subclass 44.

Group XXXI. Claims 41, 44-49, 52-57 and 60-64, drawn to a method of treating an autoimmune disease by administering a ribozyme or a DNA molecule which encodes it, wherein said nucleic acid is directed against IkB, classified in 514, subclass 44.

Group XXXII. Claims 41, 44-49, 52-57 and 60-64, drawn to a method of treating an autoimmune disease by administering an antisense or a DNA molecule which encodes it, wherein said nucleic acid is directed against CF-2, classified in 514, subclass 44.

Group XXXIII. Claims 41, 44-49, 52-57 and 60-64, drawn to a method of treating an autoimmune disease by administering an antisense or a DNA molecule which encodes it, wherein said nucleic acid is directed against IkB, classified in 514, subclass 44.

Group XXXIV. Claims 49-51, 54-59 and 62-64, drawn to a method

of treating autoimmunity by administering apolipoprotein B100, classified in class 424 subclass 184.1.

Group XXXV. Claims 49-51, 54-59 and 62-64, drawn to a method of treating autoimmunity by administering DNA repair factor TFIIH, classified in class 424 subclass 184.1.

Group XXXVI. Claims 49-51, 54-59 and 62-64, drawn to a method of treating autoimmunity by administering STAT transcription factor, classified in class 424 subclass 184.1.

Group XXXVII. Claims 57-59 and 62-64, drawn to a method of treating autoimmunity by administering cyclin, classified in class 424 subclass 94.1.

Group XXXVIII. Claims 57-59 and 62-64, drawn to a method of treating autoimmunity by administering cyclin dependent kinase, classified in class 424 subclass 94.1.

Group XXXIX. Claim 65, drawn to a method for screening for a modulator of LMP2 function, classified in class 435 subclass 4.

4. The inventions are distinct, each from the other because of the following reasons:

Groups I-V and XXXIX are unique methods. They differ with respect to ingredients. Detecting autoimmune diseases by detecting proteosome activity or protein ubiquination or protein phosphorylation or NFkB activity or cell survival or growth and a method of screening are all patentably distinct because each method is detecting a physically and chemically distinct product and therefore represent patentably distinct subject matter.

Groups VI-XXXVIII are unique methods. They differ with respect to ingredients. Treating autoimmune diseases with different active ingredients that are physically, biologically and chemically distinct are all patentably distinct because each method has a unique physiologically distinct active ingredients and are therefore represent patentably distinct subject matter.

Groups I-V, XXXIX and VI-X-XXXVIII are unrelated methods and are therefore patentably distinct. Methods of detection and screening are patentable distinct from methods of treatment and methods of screening, as evidenced by their separate classifications.

SPECIES

5. This application contains claims directed to the following patentably distinct species of the claimed invention.

If Applicant elects any one of Groups VI-XXXVIII

The following species election is required.

Elect **One** autoimmune disease listed in claims 40, 48, 56 and 64.

Each autoimmune disease has unique physical, chemical and biological properties, which gives each species unique enablement and search requirements. The species are therefore patentably distinct from one another.

6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for which prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 34-39, 41-47, 49-55 and 57-64 are generic.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

9. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

10. Because a search of these 39 distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the examiner.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for

examination purposes as indicated is proper.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Thursday from 8:00 am to 5:30 pm.

15. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-3014. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
March 21, 2001